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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,998	04/14/2004	Julia Billiard	2004658-0047 (AM101291)	7072
7590 12/28/2006 Patent Department Attn: C. Hunter Baker, M.D., Ph.D. Choate, Hall & Stewart LLP Two International Place Boston, MA 02110			EXAMINER XIE, XIAOZHEN	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
31 DAYS			12/28/2006	
			DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/823,998

Applicant(s)

BILLIARD ET AL.

Examiner

Xiaozhen Xie

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121.

- I. Claims 1-14 are drawn to a polynucleotide, a vector and a host cell comprising the polynucleotide, classified in class in class 435, subclass 69.1, for example.
- II. Claims 15-19 are drawn to a composition for modulating bone-related activity comprising a Ror polypeptide, classified in class 530, subclass 300, and class 514, subclass 2, for example.
- III. Claims 20-27 are drawn to a method of screening for a bone-related agent, comprising contacting an agent with a Ror molecule, and detecting Ror activity, classified in class 435, subclass 375, for example.
- IV. Claims 28-32 are drawn to a method of screening for a bone-related agent comprising contacting an agent with an isolated cell expressing an Ror promoter sequence, and detecting Ror promoter reporter activity, classified in class 536, subclass 24.3, for example.
- V. Claims 33-35 are drawn to a method of screening for agents that modulate the binding of Ror to a binding partner, classified in class 435, subclass 375, for example.
- VI. Claims 36-56 (in part), 57-59 and 66 (in part) are drawn to a method of modulating bone-related activity, or modulating Wnt-1 and Wnt-3 activity,

- in vitro*, comprising administering an agent that modulates Ror expression or activity, classified depending upon the agent used.
- VII. Claims 36-56 (in part), 60-65, and 66 (in part) are drawn to a method of modulating bone-related activity, or modulating Wnt-1 and Wnt-3 activity, *in vivo*, comprising administering an agent that modulates Ror expression or activity, classified depending upon the agent used.
- VIII. Claims 67-80 (in part), 81-82, and 86 (in part) are drawn to a method of identifying an agent for bone-related activity *in vitro*, comprising contacting an agent with a cell expressing Ror molecule, and monitoring expression or activity of Ror molecule in a cell, classified in class 435, subclass 375, for example.
- IX. Claims 67-80 (in part), 83-85, and 86 (in part) are drawn to a method of identifying an agent for bone-related activity *in vivo*, comprising contacting an agent with a cell expressing Ror molecule, and monitoring expression or activity of Ror molecule in a cell, classified in class 435, subclass 375, for example.
- X. Claims 87 and 88 are drawn to a method of linking a bioactive molecule to a cell expressing a Wnt polypeptide, classified in class 530, subclass 402, for example.
- XI. Claims 89 is drawn to a method for screening a subject for a bone-related disorder comprising measuring the expression of Ror molecule, classified in class 536, subclass 24.3, for example.

- XII. Claims 90 and 91 are drawn to a method of identifying genes that participate in bone formation, or that modulate Wnt signaling pathway, comprising measuring gene expression profile, classified in class 435, subclass 6, for example.
- XIII. Claim 92 is drawn to a method for identifying proliferating human pre-osteoblastic cells using Ror2 as a marker, classified in class 435, subclass 375, for example.

The inventions are distinct, each from each other because of the following reasons:

Inventions I and II are drawn to patentably distinct products, wherein each has a different structure and function which require separate searches, and wherein each is capable of separate manufacture and use.

The polypeptide of Invention II is related to the polynucleotide of Invention I by virtue of encoding the same. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities. Further, the protein product can be made by another and materially different process, such as by purification from the natural source, and the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Invention I and each of Inventions III, V-VII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

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806.04, MPEP § 808.01). In the instant case the polynucleotide of Invention I are not used or otherwise involved in the process of Inventions III, V-VII, X.

Invention I and each of Inventions IV, VIII, IX, XI-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method. For instance, the polynucleotide of Invention I can be used for isolating homologous genes.

Invention II and each of Inventions IV, VI-IX, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Invention I are not used or otherwise involved in the process of Inventions IV, VI-IX, XI.

Inventions II and each of Inventions III, V, X, XII, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method. For instance, the polypeptide of Invention II can be used for generating antibodies.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III-XIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and consideration of screening for a bone-related agent by contacting an agent with a Ror molecule, and detecting Ror signaling, which is not required by others. Invention IV requires search and consideration of screening for a bone-related agent by detecting Ror promoter activity, i.e., gene expression, which is not required by others. Invention V requires search and consideration of screening for agents that modulate the binding of Ror to a binding partner, which is not required by others. Invention VI requires search and consideration of modulating bone-related activity, or modulating Wnt-1 and Wnt-3 activity, *in vitro*, which is not required by others. Invention VII requires search and consideration of modulating bone-related activity, or modulating Wnt-1 and Wnt-3 activity, *in vivo*, which is not required by others. Invention VIII requires search and consideration of identifying an agent for bone-related activity using cells that express Ror molecule, *in vitro*, which is not required by others. Invention IX requires search and consideration of identifying an agent for bone-related activity using cells that express Ror molecule, *in vivo*, which is not required by others. Invention X requires search and consideration of linking a bioactive molecule to a cell expressing a Wnt polypeptide, which is not required by others. Invention XI requires search and consideration of screening a subject for a

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bone-related disorder, which is not required by others. Invention XII requires search and consideration of identifying genes that participate in bone formation, which is not required by others. Invention XIII requires search and consideration of identifying proliferating human pre-osteoblastic cells using Ror2 as a marker, which is not required by others. Therefore, a search and examination of the above methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A.) A Ror polypeptide

A-a. Ror1

A-b. Ror2

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 15, 20, 28, 36 and 67 are generic.

One species from the Ror polypeptide group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification

of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- B.) A bone-specific promoter
 - B-a. rat 3.6 kb type I collagen promoter
 - B-b. rat 1.7 kb osteocalcin promoter

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, Claim 1 is generic.

One species from the bone-specific promoter group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

C.) A viral vector: as listed in claim 10

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 9 is generic.

One species from the viral vector group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct

species of the claimed invention:

D.) A Ror activity is detected by a decrease or an increase in:

D-a. Wnt-3 signaling

D-b. Wnt-1 signaling

D-c. Ror autophosphorylation

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 20 is generic.

One species from the Ror activity group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

E.) A Ror2 binding partner is selected from the group consisting of: as listed in claim 35

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 33, 36 and 67 are generic.

One species from the Ror2 binding partner group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected

species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

F.) A method of modulating bone-related activity in a subject comprising administering an agent, wherein said agent comprises:

F-a. Ror molecules

F-b. Ror molecule binding partners

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 36 is generic.

One species from the agent group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

G.) A method of modulating bone-related activity in a subject comprising administering an agent, wherein said agent is selected from the group consisting of:

- G-a. an antibody
- G-b. a small molecule
- G-c. a peptide
- G-d. an oligopeptide
- G-e. a polypeptide
- G-f. an antisense nucleic acid
- G-g. an siRNA

G-h an ribozyme

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 36 and 67 are generic.

One species from the agent group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct

species of the claimed invention:

H.) A method of modulating bone-related activity in a subject comprising administering an agent, wherein said agent:

H-a. inhibits expression and/or activity of Ror molecule, or inhibits binding of Ror to Ror binding partners

H-b. enhances expression and/or activity of Ror molecule, or enhances binding of Ror to Ror binding partners

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 36 is generic.

One species from the agent group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably

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distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- I.) An immortalized cell line is selected from the group consisting of:
 - I-a. HOB
 - I-b. U2OS
 - I-c. SaOS-2

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 36 and 67 are generic.

One species from the cell line group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention:

J.) A method of linking a bioactive molecule to a cell expressing a Wnt polypeptide, wherein said Wnt polypeptide is selected from the group consisting of:

J-a. Wnt-1

J-b. Wnt-3

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 87 is generic.

One species from the Wnt polypeptide group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
December 13, 2006


EILEEN B. O'HARA
PRIMARY EXAMINER